I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: December 2, 2011
Electronic Signature Paul M. Zagar: /Paul M. Zagar/

Docket No.: 086016-0052
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Partha S. Banerjee et al.

Patent No.: 6,667,344

Issued: Dec. 23, 2003

For: BRONCHODILATING COMPOSITIONS AND METHODS

REQUEST FOR CERTIFICATE OF CORRECTION
PURSUANT TO 37 C.F.R. § 1.322

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Upon reviewing the above-identified patent, Patentee noted typographical errors which should be corrected.

In the Claims:

At column 1, claim number 1, line number 31, "pharmecutical" should be changed to --pharmaceutical--.

At column 1, claim number 1, line number 35, "effect" should be changed to --effective--.

At column 3, claim number 102, line number 8, "citratic" should be changed to --citric--.

At column 3, claim number 106, line number 26, "wherein the formoterol" should be changed to wherein --said-- formoterol.

At column 3, claim number 106, line number 27, "stereoisomer optically" should be changed to stereoisomer --is-- optically.

The above typographical errors were not in the application as filed by applicant, nor in the claims presented for reexamination; accordingly no fee is required in connection with correcting these errors. See, Amendment dated July 8, 2011 in the reexamination of the '344 patent (Control No. 90/010,488).

Upon further reviewing the above-identified patent, Patentee noted a typographical error by Patentee which should be corrected.

In the Claims:

At column 3, claim number 109, line number 45-46, "tartate" should be changed to --a tartrate--.

This error was found in the Amendment dated July 8, 2011 as filed by Patentee. Accordingly, please charge our Deposit Account No. 50-0417 in the amount of $100.00 covering the fee set forth in 37 CFR 1.20(a).

The error now sought to be corrected is an inadvertent typographical error the correction of which does not involve new matter or require reexamination.

Transmitted herewith is a proposed Certificate of Correction effecting all of the above-requested typographical corrections. Patentee respectfully solicits the granting of the requested Certificate of Correction.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0417, under Order No. 086016-0052.

Dated: December 2, 2011

Respectfully submitted,

Electronic signature: /Paul M. Zagar/
Paul M. Zagar
Registration No.: 52,392
MCDERMOTT WILL & EMERY LLP
Correspondence Customer Number: 20277
Attorney/Agent For Applicant

DM_US 30766588-6.086016.0052

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,667,344

APPLICATION NO. : 09/887,281

ISSUE DATE : Dec. 23, 2003

INVENTOR(S) : Partha S. Banerjee et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 1, claim number 1, line number 31, "pharmecutical" should be changed to --pharmaceutical--;

At column 1, claim number 1, line number 35, "effect" should be changed to --effective--.

At column 3, claim number 102, line number 8, "citratic" should be changed to --citric--;

At column 3, claim number 106, line number 26, "wherein the formoterol" should be changed to wherein --said-- formoterol;

At column 3, claim number 106, line number 27, "stereoisomer optically" should be changed to stereoisomer --is-- optically;

At column 3, claim number 109, line number 45-46, "tartate" should be changed to --a tartrate--.

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Dated: December 2, 2011 Electronic Signature for Paul M. Zagar: /Paul M. Zagar/

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Docket No.: 086016-0052 **PATENT**
Reexamination Control No. 90/010,488

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EX PARTE REEXAMINATION OF U.S. PATENT NO. 6,667,344

Applicant: Partha S. Banerjee, et al.

Application/Control No. 90/010,488	Customer No.: 20277
Filed: May 11, 2009	Confirmation No.: 1806
Group Art Unit: 3991	Examiner: Dwayne C. Jones

Title: BRONCHODILATING COMPOSITIONS AND METHODS

SUPPLEMENTAL RESPONSE TO OFFICE ACTION DATED MAY 19, 2011

Mail Stop EX PARTE REEXAM 7/8/2011
Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a proceeding for *ex parte* reexamination of Banerjee et al., U.S. Patent No. 6,667,344 (the '344 patent).

This is a Supplemental Response to Applicant's Response dated June 6, 2011.

In the Office Action dated May 19, 2011, the Examiner stated that the prior art rejections are withdrawn, and that this case appears to be in condition for issuance of an *Ex Parte* Reexamination Certificate, except for certain formal matters regarding how the claims were presented in the Amendment of April 7, 2011. *See*, Office Action at 2-3. This Response makes the corrections identified in the Office Action. *The June 6, 2011 Response made the corrections identified in the Office Action. This Supplemental Response corrects an issue of claim dependency, addressed below.*

Amendments to the Claims begin on page 2.

Remarks begin on page 19.

AMENDMENTS

AMENDMENTS TO THE SPECIFICATION

There are no amendments to the Specification.

AMENDMENTS TO THE CLAIMS

The '344 patent issued with claims 1-88. Claims 25, 26, 42-47, 49-60, 63, 64, 66, 67 and 75-88 are not subject to reexamination. Claims 1-24, 27-41, 48, 62, 65, and 68-74 are being reexamined. Claim 61 has been cancelled. Claims 89-120 are new. In original claims 11 and 28, the prime symbol, as in PIPES (piperazine-N,N'-bis(2-ethanesulfonic acid)), for example, was missing in the previous amendment and has been added here to conform to the claims in the original patent.

Claims 5, 22-24, 39-41 and 89-91 are objected to in the Office Action of May 19, 2011.

The listing of claims, beginning on page 3 below, will replace all prior versions and listings of claims in this reexamination application. Each amendment to the claims herein is being made relative to the originally patented claims and not to any previous amendment. Brackets (not strikethroughs) are used for matter to be omitted from a claim and underlining is used for added matter. *See* 37 C.F.R. §1.530(f)(1)(2).

In response to the Office Action of May 19, 2011, the claims are labeled using status identifiers relative to the issued patent: Original, Amended, Cancelled, or New.

In this Supplemental Amendment, the dependency of claim 2 has been amended back to the original claim of the patent.

Listing of Claims

1. (Amended) A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable [fluid] aqueous solution, wherein the composition is stable during long term storage, [the fluid comprises water, and] the composition is formulated at a concentration effective for bronchodilation by nebulization, and the composition is suitable for direct administration to a subject in need thereof, without propellant and without dilution of the composition prior to administration.

2. (Original) The pharmaceutical composition of claim 1, wherein the composition has an estimated shelf-life of greater than 1 month usage time at 25° C. and greater than or equal to 1 year storage time at 5° C.

3. (Original) The pharmaceutical composition of claim 2, wherein greater than about 80% of the initial formoterol is present after 1 month usage time at 25° C. and 1 year storage time at 5° C.

4. (Original) The pharmaceutical composition of claim 1 that has been nebulized.

5. (Amended) The pharmaceutical composition of claim 1, wherein the pharmacologically suitable [fluid] aqueous solution comprises a polar solvent.

6. (Original) The pharmaceutical composition of claim 5, wherein the polar solvent is a protic solvent.

7. (Original) The pharmaceutical composition of claim 6, further comprising a tonicity adjusting agent.

8. (Original) The pharmaceutical composition of claim 7, wherein the tonicity adjusting agent is ammonium carbonate, ammonium chloride, ammonium lactate, ammonium nitrate, ammonium phosphate, ammonium sulfate, ascorbie acid, bismuth sodium tartrate, boric acid, calcium chloride, calcium disodium edetate, calcium gluconate, calcium lactate, citric acid, dextrose, diethanolamine, dimethylsulfoxide, edetate disodium, edetate trisodium monohydrate, fluorescein

sodium, fructose, galactose, glycerin, lactic acid, lactose, magnesium chloride, magnesium sulfate, mannitol, polyethylene glycol, potassium acetate, potassium chlorate, potassium chloride, potassium iodide, potassium nitrate, potassium phosphate, potassium sulfate, propylene glycol, silver nitrate, sodium acetate, sodium bicarbonate, sodium biphosphate, sodium bisulfite, sodium borate, sodium bromide, sodium cacodylate, sodium carbonate, sodium chloride, sodium citrate, sodium iodide, sodium lactate, sodium metabisulfite, sodium nitrate, sodium nitrite, sodium phosphate, sodium propionate, sodium succinate, sodium sulfate, sodium sulfite, sodium tartrate, sodium thiosulfate, sorbitol, sucrose, tartaric acid, triethanolamine, urea, urethan, uridine or zinc sulfate.

9. (Original) The pharmaceutical composition of claim 8, wherein the tonicity adjusting agent is sodium chloride.

10. (Amended) The pharmaceutical composition of claim 1, wherein the pharmacologically suitable [fluid] aqueous solution comprises a buffer.

11. (Original) The pharmaceutical composition of claim 10, wherein the buffer is citric acid/phosphate, acetate, barbital, borate, Britton-Robinson, cacodylate, citrate, collidine, formate, maleate, McIlvaine, phosphate, Prideaux-Ward, succinate, citrate-phosphate-borate (Teorell-Stanhagen), veronal acetate, MES (2-(N-morpholino)ethanesulfonic acid), BIS-TRIS (bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane), ADA (N-(2-acetamido)-2-iminodiacetic acid), ACES (N-(carbamoylmethyl)-2-aminoethanesulfonaic acid), PIPES (piperazine-N,N'-bis(2-ethanesulfonic acid)), MOPSO (3-(N-morpholino)-2-hydroxypropanesulfonic acid), BIS-TRIS PROPANE (1,3-bis(tris(hydroxymethyl)methylamino)propane), BES (N,N-bis(2-hydroxyethyl)-2-aminoethanesulfonaic acid), MOPS (3-(N-morpholino)propanesulfonic acid), TES (N-tris(hydroxymethyl)methyl-2-aminoethanesulfonic acid), HEPES (N-(2-hydroxyethyl) piperazine-N'-(2-ethanesulfonic acid), DIPSO (3-(N,N-bis(2-hydroxyethyl)amino)-2-hydroxy-propanesulfonic acid), MOBS (4-(N-morpholino)butanesulfonic acid), TAPSO (3-(N-tris (hydroxymethyl)methylamino)-2-hydroxy-propanesulfonic acid), tris(hydroxylmethylamino methane, HEPPSO (N-(2-hydroxyethyl)piperazine-N'-(2-hydroxypropanesulfonic acid), POPSO (piperazine-N,N'-bis(2-hydroxypropanesulfonic acid)), TEA (triethanolamine), EPPS (N-(2-

hydroxyethyl)piperazine-N'-(3-propane-sulfonic acid), TRICINE (N-tris(hydroxymethyl)methyl glycine), GLY-GLY (glycylglycine), BICINE (N,N-bis(2-hydroxyethyl)glycine), HEPBS (N-(2-hydroxyethyl)piperazine-N'-(4-butanesulfonic acid)), TAPS (N-tris(hydroxy-methyl)methyl-3-aminopropanesulfonic acid), or AMPD (2-amino-2-methyl-1,3-propanediol) buffer.

12. (Original) The pharmaceutical composition of claim 11, wherein the buffer is citrate buffer.

13. (Original) The pharmaceutical composition of claim 12, wherein the buffer concentration is from about 0.01 mM to about 150 mM.

14. (Original) The pharmaceutical composition of claim 13, wherein the buffer concentration is from about 1 mM to about 20 mM.

15. (Original) The pharmaceutical composition of claim 14, wherein the buffer concentration is about 5 mM.

16. (Original) The pharmaceutical composition of claim 8, wherein the ionic strength of the composition is about 0 to about 0.4.

17. (Original) The pharmaceutical composition of claim 16, wherein the ionic strength of the composition is about 0.05 to about 0.16.

18. (Original) The pharmaceutical composition of claim 1, wherein the pH of the composition is about 2.0 to about 8.0.

19. (Original) The pharmaceutical composition of claim 18, wherein the pH of the composition is about 4.0 to about 6.0.

20. (Original) The pharmaceutical composition of claim 19, wherein the pH of the composition is about 4.5 to about 5.5.

21. (Original) The pharmaceutical composition of claim 20, wherein the pH of the composition is about 5.0.

22. (Amended) The pharmaceutical composition of claim 1, wherein the formoterol free base concentration is about 5 μg/mL to about [2 mg/mL] 50 μg/mL.

23. (Amended) The pharmaceutical composition of claim 22, wherein the formoterol free base concentration is about [10] 5 μg/mL to about [1 mg/mL] 10 μg/mL.

24. (Amended) The pharmaceutical composition of claim [23] 22, wherein the formoterol free base concentration is about [50] 10 μg/mL to about [200] 50 μg/mL.

25. (Amended) The pharmaceutical composition of claim [24] 1, wherein the formoterol free base concentration is about 59 μg/mL.

26. (Amended) The pharmaceutical composition of claim [24] 1, wherein the formoterol free base concentration is about 118 μg/mL.

27. (Original) The pharmaceutical composition of claim 8, further comprising a buffer.

28. (Original) The pharmaceutical composition of claim 27, wherein the buffer is citric acid/phosphate, acetate, barbital, borate, Britton-Robinson, cacodylate, citrate, collidine, formate, maleate, McIlvaine, phosphate, Prideaux-Ward, succinate, citrate-phosphate-borate (Teorell-Stanhagen), veronal acetate, MES (2-(N-morpholino)ethanesulfonic acid), BIS-TRIS (bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane), ADA (N-(2-acetamido)-2-iminodiacetic acid), ACES (N-(carbamoylmethyl)-2-aminoethanesulfonaic acid), PIPES (piperazine-N,N'-bis(2-ethanesulfonic acid)), MOPSO (3-(N-morpholino)-2-hydroxypropanesulfonic acid), BIS-TRIS PROPANE (1,3-bis(tris(hydroxymethyl)methylamino)propane), BES (N,N-bis(2-hydroxyethyl)-2-aminoethanesulfonaic acid), MOPS (3-(N-morpholino)propanesulfonic acid), TES (N-tris(hydroxymethyl)methyl-2-aminoethanesulfonic acid), HEPES (N-(2-hydroxyethyl) piperazine-

N'-(2-ethanesulfonic acid), DIPSO (3-(N,N-bis(2-hydroxyethyl)amino)-2-hydroxy-propanesulfonic acid), MOBS (4-(N-morpholino)butanesulfonic acid), TAPSO (3-(N-tris (hydroxymethyl)methylamino)-2-hydroxy-propanesulfonic acid), tris(hydroxymethylamino-methane, HEPPSO (N-(2-hydroxyethyl)piperazine-N'-(2-hydroxy-propanesulfonic acid), POPSO (piperazine-N,N'-bis(2-hydroxypropanesulfonic acid)), TEA (triethanolamine), EPPS (N-(2-hydroxyethyl)piperazine-N'-(3-propane-sulfonic acid), TRICINE (N-tris(hydroxymethyl)methyl-glycine), GLY-GLY (glycylglycine), BICINE (N,N-bis(2-hydroxyethyl)glycine), HEPBS (N-(2-hydroxyethyl)piperazine-N'-(4-butanesulfonic acid)), TAPS (N-tris(hydroxy-methyl)methyl-3-aminopropanesulfonic acid), or AMPD (2-amino-2-methyl-1,3-propanediol) buffer.

29. (Original) The pharmaceutical composition of claim 28, wherein the buffer is citrate buffer.

30. (Original) The pharmaceutical composition of claim 29, wherein the buffer concentration is from about 0.01 mM to about 150 mM.

31. (Original) The pharmaceutical composition of claim 30, wherein the buffer concentration is from about 1 mM to about 20 mM.

32. (Original) The pharmaceutical composition of claim 31, wherein the buffer concentration is about 5 mM.

33. (Original) The pharmaceutical composition of claim 27, wherein the ionic strength of the composition is about 0 to about 0.4.

34. (Original) The pharmaceutical composition of claim 33, wherein the ionic strength of the composition is about 0.05 to about 0.16.

35. (Original) The pharmaceutical composition of claim 27, wherein the pH of the composition is about 2.0 to about 8.0.

36. (Original) The pharmaceutical composition of claim 35, wherein the pH of the composition is about 4.0 to about 6.0.

37. (Original) The pharmaceutical composition of claim 36, wherein the pH of the composition is about 4.5 to about 5.5.

38. (Original) The pharmaceutical composition of claim 37, wherein the pH of the composition is about 5.0.

39. (Amended) The pharmaceutical composition of claim 27, wherein the formoterol free base concentration is about 5 μg/mL to about [2 mg/mL] 50 μg/mL.

40. (Amended) The pharmaceutical composition of claim 39, wherein the formoterol free base concentration is about [10] 5 μg/mL to about [1 mg/mL] 10 μg/mL.

41. (Amended) The pharmaceutical composition of claim [40] 39, wherein the formoterol free base concentration is about [50] 10 μg/mL to about [200] 50 μg/mL.

42. (Amended) The pharmaceutical composition of claim [41] 27, wherein the formoterol free base concentration is about 59 μg/mL.

43. (Amended) The pharmaceutical composition of claim [41] 27, wherein the formoterol free base concentration is about 118 μg/mL.

44. (Original) The pharmaceutical composition of claim 25 that has been nebulized.

45. (Original) The pharmaceutical composition of claim 26 that has been nebulized.

46. (Original) The pharmaceutical composition of claim 42 that has been nebulized.

47. (Original) The pharmaceutical composition of claim 43 that has been nebulized.

48. (Original) The pharmaceutical composition of claim 27 that has been nebulized.

49. (Original) The pharmaceutical composition of claim 42, wherein the buffer is citrate buffer.

50. (Original) The pharmaceutical composition of claim 42, wherein the buffer concentration is about 5 mM.

51. (Original) The pharmaceutical composition of claim 42, wherein the ionic strength of the composition is about 0.05 to about 0.16.

52. (Original) The pharmaceutical composition of claim 42, wherein the pH of the composition is about 5.0.

53. (Original) The pharmaceutical composition of claim 42, wherein the buffer is citrate buffer; the buffer concentration is about 5 mM; the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

54. (Original) The pharmaceutical composition of claim 43, wherein the buffer is citrate buffer.

55. (Original) The pharmaceutical composition of claim 43, wherein the buffer concentration is about 5 mM.

56. (Original) The pharmaceutical composition of claim 43, wherein the ionic strength of the composition is about 0.05 to about 0.16.

57. (Original) The pharmaceutical composition of claim 43, wherein the pH of the composition is about 5.0.

58. (Original) The pharmaceutical composition of claim 43, wherein the buffer is citrate buffer; the buffer concentration is about 5 mM; the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

59. (Original) The pharmaceutical composition of claim 53 that has been nebulized.

60. (Original) The pharmaceutical composition of claim 58 that has been nebulized.

61. (Cancelled) [A nebulized solution, comprising formoterol or a derivative thereof in a pharmacologically suitable fluid.]

62. (Original) A combination, comprising: (a) the pharmaceutical composition of claim 1 formulated for single dosage administration; and (b) a vial.

63. (Original) The composition of claim 62, wherein the aqueous composition comprises (a) formoterol free base at a concentration of about 59 μg/mL; (b) aqueous saline comprising sodium chloride; and (c) citrate buffer at a concentration of about 5 mM; wherein the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

64. (Original) The combination of claim 62, wherein the aqueous composition comprises (a) formoterol free base at a concentration of about 118 μg/mL; (b) aqueous saline comprising sodium chloride; and (c) citrate buffer at a concentration of about 5 mM; wherein the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

65. (Original) An article of manufacture, comprising packaging material, an aqueous composition comprising the composition of claim 1 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.

66. (Original) An article of manufacture, comprising packaging material, the composition of claim 53 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.

67. (Original) An article of manufacture, comprising packaging material, the composition of claim 58 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.

68. (Original) The pharmaceutical composition of claim 1, further comprising one or more of (a) to (j) as follows: (a) a β_2-adrenoreceptor agonist; (b) a dopamine (D_2) receptor agonist; (c) an IL-5 inhibitor; (d) an antisense modulator of IL-5; (e) a tryptase inhibitor; (f) a tachykinin receptor antagonist; (g) milrinone or milrinone lactate; (h) a leukotriene receptor antagonist; (i) a 5-lypoxygenase inhibitor; or (j) an anti-IgE antibody.

69. (Original) The pharmaceutical composition of claim 11, wherein the buffer comprises citric acid/phosphate buffer, acetate buffer, citrate buffer or phosphate buffer.

70. (Original) The pharmaceutical composition of claim 27, wherein the buffer comprises citric acid/phosphate buffer, acetate buffer, citrate buffer or phosphate buffer.

71. (Original) The pharmaceutical composition of claim 13, wherein the buffer concentration is from about 1 mM to about 50 mM.

72. (Original) The pharmaceutical composition of claim 71, wherein the buffer concentration is about 20 mM.

73. (Original) The pharmaceutical composition of claim 30, wherein the buffer concentration is from about 1 mM to about 50 mM.

74. (Original) The pharmaceutical composition of claim 73, wherein the buffer concentration is about 20 mM.

75. (Original) The pharmaceutical composition of claim 42, wherein the buffer concentration is about 20 mM.

76. (Original) The pharmaceutical composition of claim 42, wherein the buffer is citrate buffer; the buffer concentration is about 20 mM; the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

77. (Original) The pharmaceutical composition of claim 43, wherein the buffer concentration is about 20 mM.

78. (Original) The pharmaceutical composition of claim 43, wherein the buffer is citrate buffer; the buffer concentration is about 20 mM; the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

79. (Original) The pharmaceutical composition of claim 76 that has been nebulized.

80. (Original) The pharmaceutical composition of claim 78 that has been nebulized.

81. (Original) The combination of claim 62, wherein the aqueous composition comprises (a) formoterol free base at a concentration of about 59 μg/mL; (b) aqueous saline comprising sodium chloride; and (c) citrate buffer at a concentration of about 20 mM; wherein the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

82. (Original) The combination of claim 62, wherein the aqueous composition comprises (a) formoterol free base at a concentration of about 118 μg/mL; (b) aqueous saline comprising sodium chloride; and (c) citrate buffer at a concentration of about 20 mM; wherein the ionic strength of the composition is about 0.05 to about 0.16; and the pH of the composition is about 5.0.

83. (Original) The pharmaceutical composition of claim 1, further comprising an anticholinergic agent.

84. (Original) The pharmaceutical composition of claim 83, wherein the anticholinergic agent is ipratropium bromide, oxitropium bromide, atropine methyl nitrate, tiotropium bromide or glycopyrronium bromide.

85. (Original) The pharmaceutical composition of claim 84, wherein the anticholinergic agent is ipratropium bromide.

86. (Original) The pharmaceutical composition of claim 85, wherein the ipratropium bromide is present at a concentration of about 5 μg/mL to about 5 mg/mL.

87. (Original) The pharmaceutical composition of claim 84, wherein the anticholinergic agent is tiotropium bromide.

88. (Original) The pharmaceutical composition of claim 85, wherein the tiotropium bromide is present at a concentration of about 5 μg/mL to about 5 mg/mL.

89. (New) A pharmaceutical composition comprising a single unit dosage form, the dosage form comprising a single use container, the contents of the container comprising about 2 mL of an aqueous solution comprising formoterol, a pharmaceutically acceptable salt thereof, or hydrate of said formoterol or salt, wherein the concentration of said formoterol, salt, or hydrate is equivalent to about 5 μg/mL to about 50 μg/mL of formoterol free base in the solution, and the composition is

suitable for direct administration by nebulization without dilution for bronchodilation to a subject in need thereof, and is stable during long term storage.

90. (New) A composition according to claim 89, wherein the concentration of the formoterol, salt or hydrate is equivalent to about 5 μg/mL to about 10 μg/mL of formoterol free base in the solution.

91. (New) A composition according to claim 89, wherein the concentration of the formoterol, salt or hydrate is equivalent to about 10 μg/mL to about 50 μg/mL of formoterol free base in the solution.

92. (New) A pharmaceutical composition according to claim 89, wherein the salt is a tartrate.

93. (New) A pharmaceutical composition according to claim 89, wherein the salt is a fumarate.

94. (New) A pharmaceutical composition according to claim 89, wherein the nebulization is conducted in a jet nebulizer.

95. (New) A pharmaceutical composition according to claim 89, wherein the subject is human.

96. (New) A pharmaceutical composition as defined in claim 89, wherein the nebulization is conducted in an ultrasonic nebulizer.

97. (New) A pharmaceutical composition as defined in claim 89, wherein the nebulization is conducted in an electromagnetic nebulizer.

98. (New) A pharmaceutical composition according to claim 89 wherein the aqueous solution comprises a saline solution.

99. (New) A pharmaceutical composition according to claim 98, wherein the saline solution is isotonic.

100. (New) A pharmaceutical composition according to claim 89, wherein the solution further comprises a citrate buffer.

101. (New) A pharmaceutical composition according to claim 100, wherein the citrate buffer comprises sodium citrate.

102. (New) A pharmaceutical composition according to claim 100, wherein the citrate buffer comprises citric acid and sodium citrate.

103. (New) A pharmaceutical composition according to claim 89, wherein the dosage form comprises an aqueous solution that is sterile.

104. (New) A pharmaceutical composition according to claim 89, wherein the formoterol, salt or hydrate is provided as a mixture of enantiomers or stereoisomers of formoterol, or a salt or a hydrate thereof.

105. (New) A pharmaceutical composition according to claim 89, wherein the formoterol, salt or hydrate is provided substantially as a single enantiomer or stereoisomer of formoterol, or a salt or a hydrate thereof.

106. (New) A pharmaceutical composition according to claim 105, wherein said formoterol, salt, or hydrate provided substantially as a single enantiomer or stereoisomer is optically pure.

107. (New) A pharmaceutical composition according to claim 105, wherein the formoterol, salt, or hydrate consists of the free base, a salt or a hydrate of the enantiomer or stereoisomer 2-hydroxy-5-((1R)-1-hydroxy-2-(((1R)-2-(p-methoxyphenyl)-1-methylethyl)amino) ethyl) formanilide.

108. (New) A pharmaceutical composition according to claim 106, wherein the formoterol, salt, or hydrate consists of the free base, a salt or a hydrate of the enantiomer or stereoisomer

2-hydroxy-5-((1R)-1-hydroxy-2-(((1R)-2-(p-methoxyphenyl)-1-methylethyl)amino) ethyl) formanilide.

109. (New) A pharmaceutical composition according to claim 108, wherein the formoterol, salt, or hydrate consists of a tartate salt of the enantiomer or stereoisomer

2-hydroxy-5-((1R)-1-hydroxy-2-(((1R)-2-(p-methoxyphenyl)-1-methylethyl)amino) ethyl) formanilide.

110. (New) A pharmaceutical composition according to claim 108, wherein the formoterol, salt, or hydrate consists of a fumarate salt of the enantiomer or stereoisomer

2-hydroxy-5-((1R)-1-hydroxy-2-(((1R)-2-(p-methoxyphenyl)-1-methylethyl)amino) ethyl) formanilide.

111. (New) A pharmaceutical composition according to claim 105, wherein the formoterol, salt or hydrate consists of a formoterol tartrate or a formoterol fumarate.

112. (New) A pharmaceutical composition according to claim 111, wherein the formoterol, salt or hydrate consists of a formoterol fumarate dihydrate.

113. (New) A pharmaceutical composition according to claim 111, wherein the formoterol, salt or hydrate consists of a formoterol tartrate.

114. (New) A pharmaceutical composition comprising a single unit dosage form, the dosage form comprising a single use container, the contents of the container comprising about 2 mL of a sterile isotonic saline solution comprising a pharmaceutically acceptable salt of formoterol or a hydrate thereof and a citrate buffer, wherein the concentration of the formoterol salt is equivalent to about 5-50 µg formoterol free base per mL of solution, the dosage form is suitable for long term storage of the solution, and the solution does not require dilution before the administration by

nebulization of a therapeutically effective amount for bronchodilation of the formoterol salt or hydrate to a human subject in need thereof.

115. (New) A pharmaceutical composition according to claim 114, wherein the salt is a formoterol fumarate or a formoterol tartrate.

116. (New) A pharmaceutical composition according to claim 115, wherein the salt is a formoterol fumarate dihydrate.

117. (New) A pharmaceutical composition according to claim 115, wherein the salt is a formoterol tartrate.

118. (New) A pharmaceutical composition comprising a single unit dosage form, the dosage form comprising a single use container, the contents of the container comprising about 2 mL of a sterile isotonic saline solution comprising a pharmaceutically acceptable salt of

2-hydroxy-5-((1R)-1-hydroxy-2-(((1R)-2-(p-methoxyphenyl)-1-methylethyl)amino)ethyl) formanilide (formoterol) or a hydrate thereof

and a citrate buffer,

wherein the concentration of the formoterol salt is equivalent to about 5-50 μg formoterol free base per mL of solution,

the dosage form is suitable for long term storage of the solution, and

the solution does not require dilution before the administration by nebulization of a therapeutically effective amount for bronchodilation of the formoterol salt to a human subject in need thereof.

119. (New) A pharmaceutical composition according to claim 114, wherein the concentration of the formoterol salt is equivalent to about 5-10 μg formoterol free base per mL of solution.

120. (New) A pharmaceutical composition according to claim 118, wherein the concentration of the formoterol salt is equivalent to about 5-10 µg formoterol free base per mL of solution.